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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/774,751

02/09/2004

Jerry R. Grychowski

6298-449

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757 7590 06/24/2009
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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

06/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/774,751 | Applicant(s) GRYCHOWSKI ET AL. | |
| | Examiner NIHIR PATEL | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01.05.2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,24-30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-10,28-30 and 33-35 is/are allowed.
- 6) ☒ Claim(s) 11-14,24-27 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04.23.2009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3-14, 24-30 and 32-35 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

2. The examiner acknowledges the amendment filed on January 5th, 2009. The amendment comprises amending claims 1, 30, 33 and 35; and cancelling claims 2, 15-23 and 31.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **11-14, 24-27 and 32** are rejected under 35 U.S.C. 102(b) as being anticipated by Kremer, Jr. (US 4,803,977).

5. **As to claim 11**, Kremer teaches an apparatus that comprises a chamber **21 (see figure 1; col. 3 lines 15-25))** housing defining an interior space and comprising an input end (**see figure 1**) and an output end (**see figure 1**); a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve **15 (see figure 1; column 3 lines 15-25)** operative to permit a flow of gases into the interior space of the chamber housing; an inhalation conduit communicating with the output of the chamber, the inhalation conduit adapted to transmit medication to the patient (**see col. 3 lines 35-45**); an exhaust conduit **33** communicating with the

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first inhalation conduit; a one way exhaust valve **31** located in the exhaust conduit, the one way exhaust valve adapted to prevent backflow of gas from the exhaust conduit into the first inhalation conduit (**see figure 1; col. 3 lines 50-60**); and an adaptor **26** connected to the output end of the chamber housing (**see figure 1**) and comprising a first portion **25** defining at least a portion of the inhalation conduit and a second portion **30** defining at least a portion of the exhaust conduit **33**, wherein the one way exhaust valve **31** is positioned in the second portion of the adaptor, and further comprising an exhaust line connected to the second portion and defining at least a portion of the exhaust conduit **33**, wherein the first portion defines a first passageway having a first and second passageway, and wherein the adapter further defines a third passageway communicating between the first passageway and the second passageways, wherein the one way exhaust valve is disposed in the second passageway (**see figure 1**).

6. **As to claim 12**, Kremer teaches an apparatus that further comprises a connector member connecting the second portion and the exhaust line (**see figure 1**).

7. **As to claim 13**, Kremer teaches an apparatus wherein the first channel has a first cross sectional area and the second channel has a second cross sectional area, wherein the second cross sectional area is greater than the first cross sectional are (**see figure 1**).

8. **As to claim 14**, Kremer teaches an apparatus that further comprises a shoulder formed at the interface of the first and second channels, and wherein the third passageway communicates with the second channel at the shoulder (**see figure 1**).

9. **As to claims 24**, Kremer teaches method steps of transmitting oxygen from a ventilator through a holding chamber and inhalation conduit to a patient during an inhalation sequence of breathing cycle (**see col. 3 lines 30-40**); introducing the medication into the holding chamber **21**

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(**see col. 3 lines 15-25**); preventing a substantial transmission of an exhaust gas into the holding chamber during an exhalation sequence of the breathing cycle (**see col. 3 lines 25-35**); transmitting a substantial portion of the exhaust gas into an exhaust conduit **33** during the exhalation sequence (**see col. 3 lines 50-60**); and preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences of subsequent breathing cycles (**see col. 3 lines 45-55**); and transmitting the substantial portion of the exhaust gas from exhaust conduit to the ventilator during the exhalation sequence (**see columns 3 lines 55-65**).

10. **As to claim 25**, Kremer teaches method steps of preventing said substantial transmission of said exhaust gas into said holding chamber during said exhalation sequence comprises creating a back pressure in said holding chamber (**see col. 3 lines 45-60**).

11. **As to claim 26**, Kremer teaches method steps of creating said back pressure in said holding chamber comprises providing a one-way valve between said gas source and said holding chamber, and preventing the flow of said exhaust gas from said holding chamber toward said gas source with said one-way valve (**see col. 3 lines 10-20 and lines 45-60**).

12. **As to claim 27**, Kremer teaches method steps of preventing a substantial transmission of said exhaust gas from said exhaust conduit into said inhalation conduit during subsequent inhalation sequences comprises providing a one-way valve in said exhaust conduit, and preventing the flow of said exhaust gas from said exhaust conduit to said inhalation conduit with said one-way valve (**see col. 3 lines 25-35 and lines 45-60**).

13. **As to claim 32**, Kremer teaches method steps of providing a one-way valve between said gas source and said holding chamber comprises providing an inhalation conduit communicating

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with an input end of said holding chamber (**see col. 3 lines 15-25**), wherein said one-way valve is disposed in said inhalation conduit, and wherein said introducing said medication into said holding chamber comprises introducing said medication into said inhalation conduit between said holding chamber and said one-way valve (**see col. 3 lines 25-35**).

Allowable Subject Matter

14. Claims **1, 3-10, 28-30 and 33-35** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose the one way inhalation valve permits one way flow of oxygen from the second inhalation conduit into the interior space of the chamber housing and a second inhalation conduit communicating with the interior space of the chamber housing at the input end, wherein the second inhalation conduit has a second cross sectional area defined substantially perpendicular to the longitudinal flow direction at the input end, wherein the second cross-sectional area is less than the first cross sectional area, wherein the one way inhalation valve is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

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/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772